Therapeutics Advisory Group

Improving lives together
Norfolk and Waveney Integrated Care System

Prescribing Guidance Update

Use of off-label testosterone in women for hypoactive sexual disorder during the menopause

January 2024 v3.0

Off-label use of testosterone in women for hypoactive sexual disorder during the menopause has been given a classification of **ADVICE - GP may initiate testosterone following specialist recommendation** in line with national guidance – **NICE NG23 – Menopause Diagnosis and Management** GP will refer patient to a menopause specialist. They will review patient notes, blood results and other relevant information. If testosterone treatment is suitable, they will notify GP of required preparation, dose and monitoring requirements

A 'Specialist' can be defined as a Consultant Endocrinologist / Gynaecologist or a GP with a special interest.

ADVICE - GP may initiate testosterone following specialist recommendation

Background to treatment

In postmenopausal women who are distressed by low libido and where there is no other identifiable cause (e.g. physical and psychosocial factors and medications), and where oestrogen replacement therapy (ERT) alone has not been effective, testosterone therapy can be considered. There is currently **no licensed treatment** available in the UK for women who complain of lack of libido associated with the menopause following the withdrawal of testosterone implants and patches from the market. Standard ERT including tibolone should always be considered. When this fails to resolve symptoms, testosterone replacement has historically been used as an alternative option.

NICE have published 'Menopause - Diagnosis and Management NG23' (updated December 2019) regarding altered sexual function which states the following:

1.4.8 Consider testosterone supplementation for menopausal women with low sexual desire if HRT alone is not effective.

However, it notes that at the time of original publication (November 2015), testosterone did not have a UK marketing authorisation for this indication in women. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented.

The British Menopause Society (BMS) guidance also acknowledges that there are no commercially available products for testosterone replacement in women in the UK.

Although the NICE NG23 guideline recommends that systemic HRT should be prescribed before a trial of testosterone, there is trial data in women with Hypoactive Sexual Desire Disorder which indicate that testosterone used without systemic oestrogen, is equally effective and safe.

Form and strength of preparation

- Testogel® 40.5mg in 2.5g sachets
- Tostran® (testosterone 2% in a multi-dose pump action container)

Side effects, interactions and contraindications

Side Effects	Drug Interactions	Contraindications
Testogel®	Testogel®	Testogel®
Tostran®	Tostran®	Tostran®

Dose, administration and supply

Treatment can be initiated by a GP following advice from specialist.

Dose range: 3-10mg/day (rarely over 7mg/day), as advised by specialist on case-by-case basis and individual circumstances. Dose titrated according to FAI levels. It should be taken into account that physiological testosterone serum levels lower with increasing age.

Two topical products are included for (off-label) use in women: (as per British Menopause Society)

- **Testogel® (40.5mg in 2.5g sachets)**
  - Starting dose 1/8 of a sachet/day = approx. 5mg/day i.e. each sachet should last 8 days. (new formulation)
    Apply a small pea-size amount each day. Seal sachet with a clip between uses. A box of 30 sachets should last 240 days. Do not prescribe pump version of Testogel

- **Tostran® (testosterone 2% in a multi-dose pump action container)**
  - One depression of the pump gives 0.5g which is equal to = 10mg. This should be used on alternate days, so each canister should last 240 days.
  - The gel should be applied to clean, dry, intact skin. It should be rubbed in gently with one finger until dry, then the application site should be covered, preferably with loose clothing. Hands should then be washed with soap and water.
  - The dose can be applied to the abdomen (entire dose over an area of at least 10 by 30 cm), or to both inner thighs (one half of the dose over an area of at least 10 by 15 cm for each inner thigh).

Daily rotation between the abdomen and inner thighs is recommended to minimize application site reactions.

The BMS advise that response may not be immediate, taking 8-12 weeks in some instances for the effect to become clinically significant. It is therefore advised that treatment should trialed for a minimum of 3 months and maximally for 6 months before being discontinued due to lack of efficacy.

Treatment should include regular monitoring and it should be an informed decision between physician and patient if treatment is to be continued beyond 24 months

GP prescribing responsibilities

- Prescribe at request of specialist.
- Discuss with patient that it is an off-label use of testosterone.
- Undertake clinical assessment and baseline monitoring
- Review any new concurrent medications for potential interactions.
- Notification to specialist of any changes in the patient's condition, any adverse drug reactions, or if the patient fails to attend for blood monitoring.
- Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.
- Report adverse events to the specialist and MHRA via the yellow card scheme.
- Stop treatment on the advice of the specialist.

GP monitoring responsibilities

Baseline

Baseline blood tests to be taken before starting testosterone replacement therapy – FAI and FBC. Blood pressure and BMI are also measured.

Formula to calculate Free Androgen Index (FAI) – Total testosterone / Sex hormone binding globulin (SHBG) x 100%

Monitoring	Frequency
• Free Androgen Index, FBC • LFTs/U&Es and lipids: only if indicated by the specialist • BP and BMI to be assessed at baseline and when required thereafter	• FAI: If above 5%, specialist to review • Repeat FAI after 3 months and then every 12 months - should not be >5%. • FBC to be measured annually

Ongoing

Monitoring	Frequency
• FAI • Full blood count (FBC)	• Annually • If Hb greater than 18 g/dL discuss venesection with haematologist • FAI- annually should be <5%; If above 5% contact specialist for further advice

Patient responsibilities

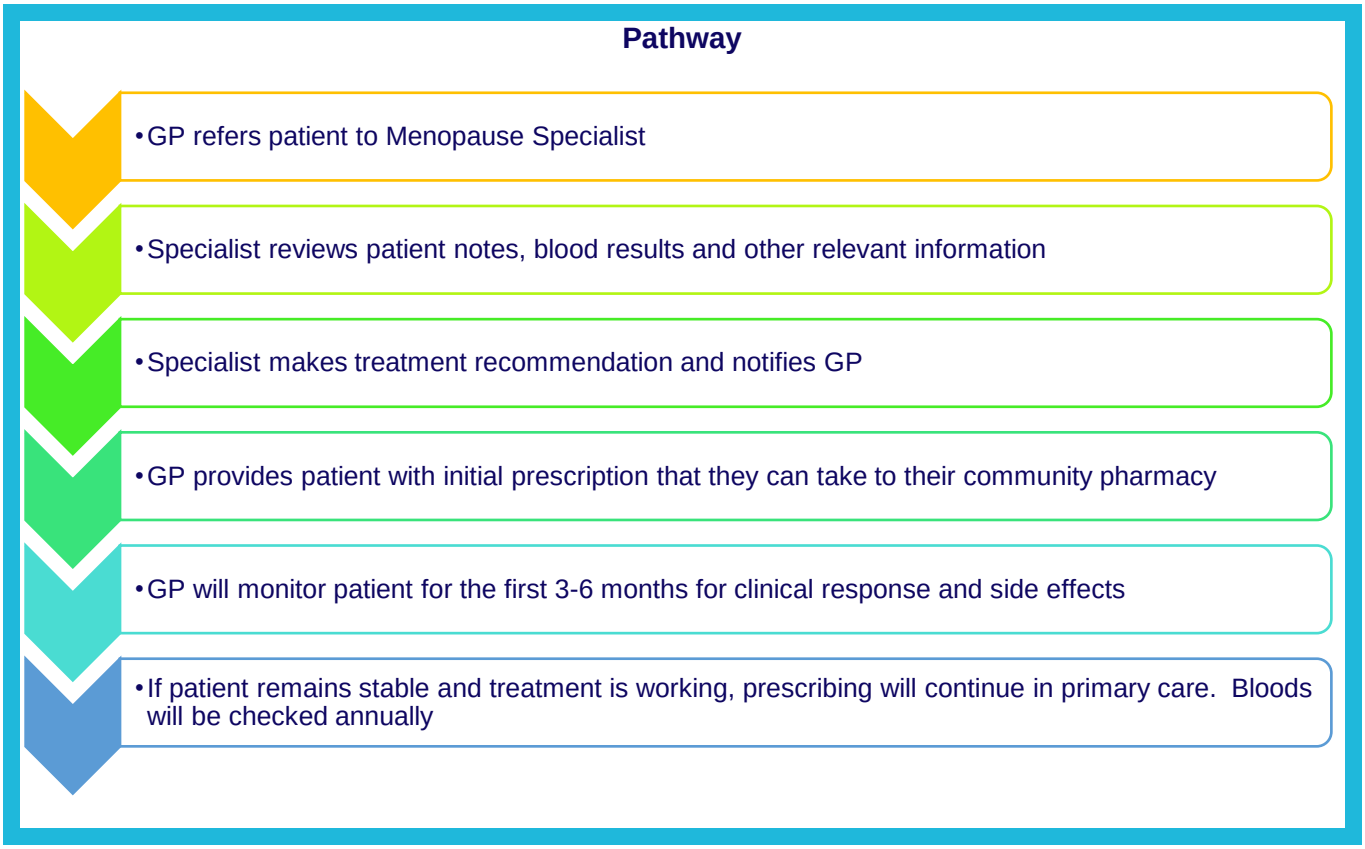
- Report any concerns or adverse effects to the specialist or GP.
- Attend appointments for blood tests, clinical review and monitoring.

Indications for referral back to specialist

Abnormal test results should be discussed with the specialist.

Additional information

Available data does not support use of testosterone in peri-menopause, and testosterone should not be used to treat depression or bone loss or to prevent cognitive decline.



Title	Prescribing Guidance - Use of off-label testosterone in women for hypoactive sexual disorder during the menopause
Description of policy	*To inform healthcare professionals*
Scope	*Norfolk and Waveney Integrated Care System*
Prepared by	Norfolk and Waveney ICB Medicines Optimisation Team
Impact Assessment (Equalities and Environmental)	*Please indicate impact assessment outcome:* *Positive impact* *Adverse impact - low - action plan completed as per guidance* *Adverse impact - medium - action plan completed as per guidance* *Adverse impact - high - action plan completed as per guidance* *No impact* ***No policy will be approved without a completed equality impact assessment***
Other relevant approved documents	
Evidence base / Legislation	Level of Evidence: *A. based on national research-based evidence and is considered best evidence* ***B. mix of national and local consensus*** *C. based on local good practice and consensus in the absence of national research based information.*
Dissemination	Is there any reason why any part of this document should not be available on the public web site? ☐ Yes / No ☒
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Review date and by whom	TAG – Jan 2026
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1.0	Jen Carroll, TAG Lead Technician, AGEM CSU	First draft for consideration by the TAG. Adapted from SCA document by BSW APC: BaNES, Swindon & Wiltshire (BSW)	Nov 2021
1.1	Jen Carroll, TAG Lead Technician, AGEM CSU	Contact details and FAI calculation added following TAG discussion	Dec 2021
1.2	Jen Carroll, TAG Lead Technician, AGEM CSU	Final version agreed by TAG and D+TC. Ratified by CCG Governing Body	March 2022
1.3	Jen Carroll, TAG Lead Technician, AGEM CSU	Table added at end to show process for initiation and discharge from specialist care	May 2022
1.4	Jen Carroll, TAG Lead Technician, NHS Norfolk and Waveney	Classification changed to level 0 and logo updated	July 2022
1.5	Jen Carroll, TAG Lead Technician, NHS Norfolk and Waveney	Treatment options updated	Nov 2022
2.0	Jen Carroll, TAG Lead Technician, NHS Norfolk and Waveney	Treatment options updated – Added Testogel 40.5mg in 2.5g sachets	Feb 2023
3.0	Jen Carroll, TAG Lead Technician, NHS Norfolk and Waveney	Classification amended from shared care Guidance to Advice. Content transferred to Prescribing Guidance template. Testim removed as discontinued	Jan 2024